

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor(s) : Margaret M. Ancira
Serial No. : Not Yet Assigned
Filing Date : Not Yet Assigned
Title : HYDROXY-KOJIC ACID SKIN PEEL

Group/Art Unit : Not Yet Assigned
Examiner : Not Yet Assigned
Confirmation No. : Not Yet Assigned

Atty. Docket No. : 766632-0049

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97(b)

Mail Stop Patent Application
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Madam:

In accordance with 37 C.F.R. § 1.56 and § 1.97(b), the references listed below and on the attached Form PTO/SB/08A (Substitute for Form 1449A-B/PTO) are being brought to the attention of the Examiner for consideration in connection with the examination of the above-identified patent application. The present application is a divisional of prior U.S. Application Serial No.: 09/974,743, filed October 9, 2001, which is a Continuation of U.S. Application Serial No. 09/299,788 filed February 22, 1999, which is now issued as U.S. Patent No. 6,300,369, which is a Continuation of U.S. Application Serial No. 08/795,231, filed February 10, 1997, which is now issued as U.S. Patent No. 5,874,463, and a continuation-in-part of

Certificate of Mailing Under 37 C.F.R. 1.8

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to Mail Stop Patent Application, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450, on:

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The Director is hereby authorized to charge any additional amount required, or credit any overpayment, to Deposit Account No. 19-4409.

Application Serial No. 08/328,006 filed on October 24, 1994, now abandoned, and are hereby incorporated by reference. The cited documents are already of record in the parent cases, and therefore, copies are not being submitted with the present statement pursuant to 37 C.F.R. § 1.98(d). Submission of these references is not an admission that the references constitute prior art.

U.S. PATENTS

<u>Patent No.</u>	<u>Inventor(s)</u>	<u>Issue Date</u>
3,265,571	Krezanoski	08/09/1966
3,666,863	Swanbeck	05/30/1972
3,806,593	Swanbeck	04/23/1974
3,856,934	Kligman	12/24/1974
4,278,656	Nagai et al.	07/14/1981
4,285,973	Edwards	08/25/1981
4,294,852	Wildnauer et al.	10/13/1981
4,318,907	Kligman	03/09/1982
4,369,174	Nagai	01/18/1983
4,608,370	Aronsohn	08/26/1986
4,696,813	Higa	09/29/1987
4,847,074	Hatae	07/11/1989
4,874,361	Obagi	10/17/1989
4,891,361	Hatae	01/02/1990
4,919,921	Hatae	04/24/1990
4,948,577	Hara	08/14/1990
4,985,255	Higa	01/15/1991
4,985,455	Motono	01/15/1991
4,990,330	Oyama	02/05/1991
4,990,532	Yamamoto	02/05/1991
5,043,356	Fulton, Jr.	08/27/1991
5,063,056	Yamamoto	11/15/1991
5,164,182	Meybeck	11/17/1992
5,164,185	Charpin et al.	11/17/1992
5,166,176	Obagi et al.	11/24/1992
5,244,665	Natraj et al	09/14/1993
5,262,153	Mishima et al.	11/16/1993
5,279,834	Meybeck	01/18/1994
5,378,455	Kealey et al.	01/03/1995
5,427,775	Sakai et al.	06/27/1995
5,443,840	Morancas et al.	08/22/1995
5,486,624	Yang et al.	01/23/1996

U.S. PATENTS

<u>Patent No.</u>	<u>Inventor(s)</u>	<u>Issue Date</u>
5,505,948	Rapaport	04/09/1996
5,520,918	Smith	05/28/1996
5,523,421	Yang et al.	06/04/1996
5,531,993	Griat	07/02/1996
5,540,853	Trinh et al.	07/30/1996
5,545,407	Hall et al.	08/13/1996
5,547,678	Gagnebien-Cabanne	08/20/1996
5,560,907	Sakai	10/01/1996
5,580,549	Fukuda et al.	12/03/1996
5,599,528	Igaki	02/04/1997
5,607,692	Ribier et al.	03/04/1997
5,609,875	Hadas	03/11/1997
5,637,293	Honda	06/10/1997
5,874,463	Ancira	02/23/1999
5,989,536	Deckner et al.	11/23/1999
6,197,343	Minami et al.	03/06/2001
6,300,369	Ancira	10/09/2001
6,348,200	Nakajima et al.	02/19/2002
6,348,204	Touzan	02/19/2002
6,365,137	Aust et al.	04/02/2002
6,383,523	Murad	05/07/2002
6,384,079	Yu et al.	05/07/2002
6,391,863	Philippe et al.	05/21/2002
6,403,064	Alaluf et al.	06/11/2002
6,417,226	Perricone	07/09/2002
6,495,126	Schiltz	12/17/2002
6,534,543	Ptchelintsev et al.	03/18/2003
6,544,533	Breton et al.	04/08/2003
6,590,105	Bradley et al.	07/08/2003
6,616,933	Breton et al.	09/09/2003

FOREIGN PATENTS

<u>Country</u>	<u>Patent No./Publication No.</u>	<u>Publication Date</u>
PCT	EP 0381057	08/08/1990
Europe	EP 308918	03/29/1989
Europe	EP 308919	03/29/1989
Europe	EP 345081	12/06/1989
Europe	EP 345082	12/06/1989
Japan	JP 01121205	05/12/1989

FOREIGN PATENTS

<u>Country</u>	<u>Patent No./Publication No.</u>	<u>Publication Date</u>
Japan	JP 01228908	09/12/1989
Japan	JP 01275524	11/06/1989
Japan	JP 01311011	12/15/1989
Japan	JP 02028105	01/30/1990
Japan	JP 02045408	02/15/1990
Japan	JP 02049709	02/20/1990
Japan	JP 02142714	05/31/1990
Japan	JP 02200622	08/08/1990
Japan	JP 03014507	01/23/1991
Japan	JP 03014508	01/23/1991
Japan	JP 03112915	05/14/1991
Japan	JP 3-11010	01/18/1991
Japan	JP 3-236319	02/09/1990
Japan	JP 7002643	01/06/1995
PCT	WO 93/07903	04/29/1993
PCT	WO 94/02674	02/03/1994
PCT	WO 94/15580	07/21/1994
PCT	WO 95/03781	02/09/1995

LEGAL PROCEEDINGS

A. Physician's Choice of Arizona, Inc. v. Rhonda Allison, an individual dba Rhonda Allison Skin Therapies and Rhonda Allison Clinical Enterprises, Case No. CIV99 2104 PHX SMM, U.S. District Court, District of Arizona.

1. Final Judgment (Proposed), dated April 10, 2000.
2. Permanent Injunction (proposed), dated April 10, 2000.
3. Defendant's Original Answer and Demand for Jury Trial, dated January 26, 2000.
4. First Amended Complaint for Patent Infringement and Demand for Jury Trial, filed December 7, 1999.

B. Physician's Choice of Arizona, Inc. v. Peter Thomas Roth Labs, L.L.C., Case No. CIV 99 2103 PHX PGR, U.S. District Court, District of Arizona

1. Stipulation for Entry of Final Judgment and proposed Final Judgment Order, dated February 2, 2001.
2. Settlement Agreement between Physician's Choice of Arizona, Inc. and Peter Thomas Roth Labs, L.L.C. dated January 21, 2001.

3. Defendant's Answer to First Amended Complaint and Counterclaim, dated May 3, 2000.
4. Joint Case Management Report resulting from Court's "Order Setting Scheduling Conference" filed December 17, 1999.
6. First Amended Complaint for Patent Infringement and Demand for Jury Trial, filed December 7, 1999.

C. Physician's Choice of Arizona, Inc. v. SesDerma, Inc., Case No. CIV03 0260 PHX JAT, U.S. District Court, District of Arizona

1. Complaint, filed February 7, 2003.

D. Physician's Choice of Arizona, Inc. v. Visual Changes Skin Care International, Inc., Case No. CIV03 0873 PHX RCB, U.S. District Court, District of Arizona

1. Complaint, filed May 9, 2003.

OTHER REFERENCES FROM LEGAL PROCEEDINGS

A. Physician's Choice of Arizona, Inc. v. Visual Changes Skin Care International, Inc., Case No. CIV03 0873 PHX RCB, U.S. District Court, District of Arizona

1. CANNING, C., "The Skin Care Market, pgs. 14-15, May 1994.
2. CoValence, Inc. Advertisement, CoValence, Inc. Firsts (1 pg.) (undated).
3. KLIGMAN, A., M.D., Ph.D., "Results of a Pilot Study Evaluating the Compatibility of Topical Tretinoin in Combination with Glycolic Acid," Cosmetic Dermatology, pg. 29, Vol. 6, No. 10, October 1993 (first page only).

B. Physician's Choice of Arizona, Inc. v. SesDerma, Inc., Case No. CIV03 0260 PHX JAT, U.S. District Court, District of Arizona

1. "'El Lightening Peel Autua a la vez Sobre los Depositos de Melanina y en us Sintesis" (2 pgs) (undated).
2. NAKAGAWA, M., et al., "Contact Allergy to Kojic Acid in Skin Care Products", Contact Dermatitis (1995) (5 pgs.).
3. "Nuevos Peelings con AHAs, New Peels with AHA," Piel y Dermocosmetica IberoAmericana (handwritten "1997" notation provided by defendant).

4. SERRANO SANMIGUEL, G., Form No. 1036948 documenting the presentation of HIDROQUIN to the Direccion General De Farmacia Y Productos Sanitarios (Health Department) by Gabriel Serrano Sanmiguel (March 11, 1992) (1 pg.).
5. SERRANO SANMIGUEL, G., et al., "Melasma: Nuevas Perspectivas Para Un Viejo Problema," Dermocosmetica Clinica, Vol. 4 No. 4 (undated) (1 pg.).
6. SERRANO SANMIGUEL, G., et al., "Peeling Superficial Con Acido Glucolico Neutralizado: Un Concepto Nuevo de Peeling," Dermocosemtica Clinica, 4: 243-254 (handwritten "October 1993" notation provided by defendant) (12 pgs.).
7. SesDERMA brochure, "New Generation of Pigmentation Inhibitors" (undated) (4 pgs.).
8. SesDERMA brochure, "The Most Effective Solution to Melasma or Chloasma and Other Facial Pigmentations, Depigmenting Gel" (Hydroquin) (believed to be published in 2000 or later based on references at end) (3 pgs.).
9. SesDERMA brochure, "The New Generation of Pigmentation Inhibitors" on Hydroquin and Kojicol (undated) (4 pgs.).

OTHER REFERENCES

Ancira, "Licensed to Peel," Dermascope, 26-27-1994.

Andrews, "Diseases of the Skin", Philadelphia, WB Saunders, 1928:240-248.

Bendas et al., "Propylene glycol," In: Percutaneous Penetration Enhancers, Smith et al., (Eds.), CRS Press, p. 61-77, 1995.

Cabanes, et al., "Kojic Acid, a Cosmetic Skin Whitening Agent, is a Slow-Binding Inhibitor of Catecholase Activity of Tyrosinase," J. Pharm. Pharmacol., 46:982-985, 1994.

Chiarello et al., "The TCA Masque: A New Cream Formulation Used Alone and in Combination with Jessner's Solution," Dermatologic Surgery, 22:687-690, 1996.

Cornell and Stoughton, "Correlation of the vasoconstriction assay and clinical activity in psoriasis," Arch. Dermatology, 121:63-67, 1985.

Ellis et al., "Superficial Micopeels: Glycolic Acid and Alpha-Hydroxy Acid with Kojic Acid," Facial Plastic Surgery 11(1): 15-21; 1995.

Garcia et al., "The Combination of Glycolic Acid and Hydroquinone or Kojic Acid for the Treatment of Melasma and Related Conditions," Dermatologic Surgery 22: 443-447; 1996.

Horvath, "The Light Peel," Bulletin of the Association of Military Dermatologists 18:5; 1970.

Kligman, "Cosmetics and the Skin," Wells & Lubowe, Rinehold, 1964.

Monheit, "The Jessner's + TCA peel: A Medium-Depth Chemical Peel," Journal of Dermatologic Surgery and Oncology 15(9): 945-960; 1989.

Rubin, "An Overview of Chemical Peeling," Plastic Surgery Products, Skin Care, pp. 14-15, April 1995.

Rubin, "Manual of Chemical Peels: Superficial and Medium Depth", Philadelphia, J.B. Lippincott Company, 1995: 79-88.

Sulzberger, "Dermatologic Therapy," Chicago, Year Book Medical Publishers, 1940: 76-80.

Tse, "A Clinical and Histologic Evaluation of Two Medium-Depth Peels: Glycolic Acid Versus Jessner's Trichloroacetic Acid," Dermatologic Surgery 22:781-786; 1996.

Product Name: PCA Peel® with hydroquinone. Composition: 55% ethanol/water, 15% salicylic acid, 15% lactic acid, 10% citric acid, 3% kojic acid, and 2% hydroquinone. Estimated Date of Sale: October 27, 1993.

Product Name: PCA Peel® without hydroquinone. Composition: 57% ethanol/water; 15% salicylic acid, 15% lactic acid, 10% citric acid, 3% kojic acid. Estimated Date of Sale: November 1993.

Product Name: PCA Peel® with hydroquinone and resorcinol. Composition: 52% ethanol/water, 14% lactic acid, 14% resorcinol, 15% salicylic acid, 3% kojic acid, 2% hydroquinone, and 1% citric acid. Estimated Date of Sale: May 1994.

Brody, Chemical Peeling, pp 53-73 (superficial peeling), 75-97 (medium depth peeling), and 165-170 (index) (1993).

Applicant respectfully requests that these references be made of record in the above-identified application and considered by the Examiner during prosecution of the application.

It is respectfully submitted that the present invention as claimed is patentable over the listed references.

This information disclosure statement is being filed within three months of the filing date of a national application other than a continued prosecution application under § 1.53(d) or before the mailing of a first Office Action on the merits. Accordingly, no fee is due.

Acknowledgment of receipt is respectfully requested.

Respectfully submitted,

By 

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Attorney for Applicant

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Substitute for Form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>			Complete if Known		
			Application Number:	Not Yet Assigned	
			Filing Date:	Not Yet Assigned	
			First Named Inventor:	Margaret M. Ancira	
			Group Art Unit:	Not Yet Assigned	
Examiner Name:	Not Yet Assigned				
Attorney Docket Number:	766632-0049				
Sheet	1	of	7		

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
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		3,856,934		Kligman	12/24/1974	
		4,278,656		Nagai et al.	07/14/1981	
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		4,294,852		Wildnauer et al.	10/13/1981	
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		5,043,356		Fulton, Jr.	08/27/1991	

FOREIGN PATENT DOCUMENTS

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		Office ³	Number ⁴	Kind Code ⁵ (if known)				
			EP 0381057			08/08/1990		
			EP 308918			03/29/1989		
			EP 308919			03/29/1989		
			EP 345081			12/06/1989		
			EP 345082			12/06/1989		
			JP 01121205			05/12/1989		
			JP 01228908			09/12/1989		
			JP 01275524			11/06/1989		
			JP 01311011			12/15/1989		
			JP 02028105			01/30/1990		

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¹Unique citation designation number. ²See attached Kinds of U.S. Patent Documents. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.

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		5,063,056		Yamamoto	11/15/1991	
		5,164,182		Meybeck	11/17/1992	
		5,164,185		Charpin et al.	11/17/1992	
		5,166,176		Obagi et al.	11/24/1992	
		5,244,665		Natraj et al.	09/14/1993	
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		5,427,775		Sakai et al.	06/27/1995	
		5,443,840		Morancais et al.	08/22/1995	
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		5,545,407		Hall et al.	08/13/1996	
		5,547,678		Gagnebien-Cabanne	08/20/1996	
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		5,580,549		Fukuda et al.	12/03/1996	
		5,599,528		Igaki	02/04/1997	

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			JP 02049709			02/20/1990		
			JP 02142714			05/31/1990		
			JP 02200622			08/08/1990		
			JP 03014507			01/23/1991		
			JP 03014508			01/23/1991		
			JP 03112915			05/14/1991		
			JP 3-11010			01/18/1991		
			JP 3-236319			02/09/1990		
			JP 7002643			01/06/1995		

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		Filing Date:	Not Yet Assigned		
		First Named Inventor:	Margaret M. Ancira		
		Group Art Unit:	Not Yet Assigned		
		Examiner Name:	Not Yet Assigned		
Sheet	4	of	7	Attorney Docket Number:	766632-0049

OTHER REFERENCES – NON PATENT LITERATURE DOCUMENTS AND INFORMATION			
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		Ancira, "Licensed to Peel," Dermascope, 26-27-1994.	
		Andrews, "Diseases of the Skin", Philadelphia, WB Saunders, 1928:240-248.	
		Bendas et al., "Propylene glycol," In: Percutaneous Penetration Enhancers, Smith et al., (Eds.), CRS Press, p. 61-77, 1995.	
		Cabanes, et al., "Kojic Acid, a Cosmetic Skin Whitening Agent, is a Slow-Binding Inhibitor of Catecholase Activity of Tyrosinase," J. Pharm. Pharmacol., 46:982-985, 1994.	
		Chiarello et al., "The TCA Masque: A New Cream Formulation Used Alone and in Combination with Jessner's Solution," Dermatologic Surgery, 22:687-690, 1996.	
		Cornell and Stoughton, "Correlation of the vasoconstriction assay and clinical activity in psoriasis," Arch. Dermatology, 121:63-67, 1985.	
		Ellis et al., "Superficial Micropeels: Glycolic Acid and Alpha-Hydroxy Acid with Kojic Acid," Facial Plastic Surgery 11(1): 15-21; 1995.	
		Garcia et al., "The Combination of Glycolic Acid and Hydroquinone or Kojic Acid for the Treatment of Melasma and Related Conditions," Dermatologic Surgery 22: 443-447; 1996.	
		Horvath, "The Light Peel," Bulletin of the Association of Military Dermatologists 18:5; 1970.	
		Kligman, "Cosmetics and the Skin," Wells & Lubowe, Rinehold, 1964.	
		Monheit, "The Jessner's + TCA peel: A Medium-Depth Chemical Peel," Journal of Dermatologic Surgery and Oncology 15(9): 945-960; 1989.	
		Rubin, "An Overview of Chemical Peeling," Plastic Surgery Products, Skin Care, pp. 14-15, April 1995.	
		Rubin, "Manual of Chemical Peels: Superficial and Medium Depth", Philadelphia, J.B. Lippincott Company, 1995: 79-88.	
		Sulzberger, "Dermatologic Therapy," Chicago, Year Book Medical Publishers, 1940: 76-80.	
		Tse, "A Clinical and Histologic Evaluation of Two Medium-Depth Peels: Glycolic Acid Versus Jessner's Trichloroacetic Acid," Dermatologic Surgery 22:781-786; 1996.	

Examiner Signature		Date Considered	
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		Product Name: PCA Peel® with hydroquinone. Composition: 55% ethanol/water, 15% salicylic acid, 15% lactic acid, 10% citric acid, 3% kojic acid, and 2% hydroquinone. Estimated Date of Sale: October 27, 1993.	
		Product Name: PCA Peel® without hydroquinone. Composition: 57% ethanol/water; 15% salicylic acid, 15% lactic acid, 10% citric acid, 3% kojic acid. Estimated Date of Sale: November 1993.	
		Product Name: PCA Peel® with hydroquinone and resorcinol. Composition: 52% ethanol/water, 14% lactic acid, 14% resorcinol, 15% salicylic acid, 3% kojic acid, 2% hydroquinone, and 1% citric acid. Estimated Date of Sale: May 1994.	
		Brody, Chemical Peeling, pp 53-73 (superficial peeling), 75-97 (medium depth peeling), and 165-170 (index) (1993).	
		<u>Physician's Choice of Arizona, Inc. v. Rhonda Allison, an individual dba Rhonda Allison Skin Therapies and Rhonda Allison Clinical Enterprises</u> , Case No. CIV99 2104 PHX SMM, U.S. District Court, District of Arizona, Final Judgment (Proposed), dated April 10, 2000	
		<u>Physician's Choice of Arizona, Inc. v. Rhonda Allison, an individual dba Rhonda Allison Skin Therapies and Rhonda Allison Clinical Enterprises</u> , Case No. CIV99 2104 PHX SMM, U.S. District Court, District of Arizona, Permanent Injunction (proposed), dated April 10, 2000	
		<u>Physician's Choice of Arizona, Inc. v. Rhonda Allison, an individual dba Rhonda Allison Skin Therapies and Rhonda Allison Clinical Enterprises</u> , Case No. CIV99 2104 PHX SMM, U.S. District Court, District of Arizona, Defendant's Original Answer and Demand for Jury Trial, dated January 26, 2000	
		<u>Physician's Choice of Arizona, Inc. v. Rhonda Allison, an individual dba Rhonda Allison Skin Therapies and Rhonda Allison Clinical Enterprises</u> , Case No. CIV99 2104 PHX SMM, U.S. District Court, District of Arizona, First Amended Complaint for Patent Infringement and Demand for Jury Trial, filed December 7, 1999	
		<u>Physician's Choice of Arizona, Inc. v. Peter Thomas Roth Labs, L.L.C.</u> , Case No. CIV 99 2103 PHX PGR, U.S. District Court, District of Arizona, Stipulation for Entry of Final Judgment and proposed Final Judgment Order, dated February 2, 2001	
		<u>Physician's Choice of Arizona, Inc. v. Peter Thomas Roth Labs, L.L.C.</u> , Case No. CIV 99 2103 PHX PGR, U.S. District Court, District of Arizona, Settlement Agreement between Physician's Choice of Arizona, Inc. and Peter Thomas Roth Labs, L.L.C. dated January 21, 2001	
		<u>Physician's Choice of Arizona, Inc. v. Peter Thomas Roth Labs, L.L.C.</u> , Case No. CIV 99 2103 PHX PGR, U.S. District Court, District of Arizona, Defendant's Answer to First Amended Complaint and Counterclaim, dated May 3, 2000	

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		<u>Physician's Choice of Arizona, Inc. v. Peter Thomas Roth Labs, L.L.C.</u> , Case No. CIV 99 2103 PHX PGR, U.S. District Court, District of Arizona, Joint Case Management Report resulting from Court's "Order Setting Scheduling Conference" filed December 17, 1999	
		<u>Physician's Choice of Arizona, Inc. v. Peter Thomas Roth Labs, L.L.C.</u> , Case No. CIV 99 2103 PHX PGR, U.S. District Court, District of Arizona, First Amended Complaint for Patent Infringement and Demand for Jury Trial, filed December 7, 1999	
		<u>Physician's Choice of Arizona, Inc. v. SesDerma, Inc.</u> , Case No. CIV03 0260 PHX JAT, U.S. District Court, District of Arizona, Complaint, filed February 7, 2003	
		<u>Physician's Choice of Arizona, Inc. v. Visual Changes Skin Care International, Inc.</u> , Case No. CIV03 0873 PHX RCB, U.S. District Court, District of Arizona, Complaint, filed May 9, 2003	
		CANNING, C., "The Skin Care Market, pgs. 14-15, May 1994	
		CoValence, Inc. Advertisement, CoValence, Inc. Firsts (1 pg.) (undated)	
		KLIGMAN, A., M.D., Ph.D., "Results of a Pilot Study Evaluating the Compatibility of Topical Tretinoin in Combination with Glycolic Acid," Cosmetic Dermatology, pg. 29, Vol. 6, No. 10, October 1993 (first page only)	
		"El Lightening Peel Autua a la vez Sobre los Depositos de Melanina y en us Sintesis" (2 pgs) (undated)	
		NAKAGAWA, M., et al., "Contact Allergy to Kojic Acid in Skin Care Products", Contact Dermatitis (1995) (5 pgs.)	
		"Nuevos Peelings con AHAs, New Peels with AHA," Piel y Dermocosmetica IberoAmericana (handwritten "1997" notation provided by defendant)	
		SERRANO SANMIGUEL, G., Form No. 1036948 documenting the presentation of HIDROQUIN to the Direccion General De Farmacia Y Productos Sanitarios (Health Department) by Gabriel Serrano Sanmiguel (March 11, 1992) (1 pg.)	
		SERRANO SANMIGUEL, G., et al., "Melasma: Nuevas Perspectivas Para Un Viejo Problema," Dermocosmetica Clinica, Vol. 4 No. 4 (undated) (1 pg.)	

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